SECTION 1.3

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

REGULATORY AUTHORITY

Safe Medical Devices Act of 1990, 21 CFR 807.92

COMPANY NAME/CONTACT

Alan Curtis
SURx
2675 Collier Canyon Road
Livermore, CA 94550
(925) 398-4500 (phone)
(925) 398-4509 (facsimile)
acurtis@surx.com

NAME OF DEVICE

Trade Name:	SURx RF System
Common Name:	Electrosurgical System
Device Product Code:	GEI
Classification Name:	Electrosurgical Cutting and Coagulation Device and Accessories (21 CFR 878.4400)
Device Panel:	General Surgery/Restorative Devices
Device Classification:	Class II

PREDICATE DEVICES

- SURx LP System (K011190)
- SURx TV System (K020126)

DEVICE DESCRIPTION

The SURx RF System consists of two components: the SURx Radiofrequency (RF) Generator and the SURx Applicator. The SURx Applicator connects to the Generator. The SURx Applicator is supplied sterile and intended for single use. The Applicator uses a bipolar design, such that that no return pad is required for operation. The tip of the Applicator contains a thermistor to monitor temperature at the targeted area. Two applicators are available: one for use when performing this procedure using a laparoscopic approach (LP Applicator), the other applicator is used during a transvaginal approach (TV Applicator).

The SURx Transvaginal (TV) Sizer is an optional accessory for use with the SURx TV Applicator. The SURx TV Sizer confirms the exposed area for treatment is adequate to determine if additional blunt dissection is required prior to applying the SURx TV Applicator tip on the tissue to treated.

INDICATION FOR USE STATEMENT

The SURx RF System is indicated for shrinkage and stabilization of female pelvic tissue for treatment of stress urinary incontinence due to hypermobility.

SUBSTANTIAL EQUIVALENCE COMPARISON

Technological Characteristics

There has been no change to the generator or applicators. The system is identical to that cleared in the referenced 510(k)s.

Indications for Use

Substantial equivalence for the SURx RF System is supported by the predicate devices, which has an identical indication statement.

Clinical Performance Data

The SURx RF System has been cleared for the treatment of female stress urinary incontinence. Clinical analysis was conducted to support the change in the language in the indications for use statement. Sufficient data have been gathered from clinical studies to determine that the SURx RF System performs as clinically intended and that no new issues of safety and effectiveness are introduced.

Literature Review

Published literature was reviewed on devices cleared for the treatment of female urinary incontinence as additional supporting documentation to support the modified indication for use.

CONCLUSION

Based on the design, materials, function, intended use, and clinical evaluation, the SURx RF System is substantially equivalent to the devices currently marketed under the Federal Food, Drug and Cosmetic Act. Safety and effectiveness are reasonably assured, justifying 510(k) clearance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 3 0 2002

Mr. Alan Curtis
Vice President, Clinical/Regulatory Affairs
and Quality Systems
SURx, Inc.
2675 Collier Canyon Road
Livermore, CA 94550

Re: K020952
Trade/Device Name: SURx RF System
Regulation Number: 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: March 22, 2002
Received: March 25, 2002

Dear Mr. Curtis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 1.2

INDICATIONS FOR USE STATEMENT

510(k) Number: K020952

Device Name: SURx RF System

Indications for Use:

The SURx RF System is indicated for shrinkage and stabilization of female pelvic tissue for treatment of stress urinary incontinence due to hypermobility.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X or Over-The-Counter Use_____
(Per 21 CFR 801.109)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K020952